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September 10, 2004

**VIA E-MAIL**

To: Counsel of Record for Plaintiffs\*

Re: In re Columbia University Patent Litigation, MDL No. 1592

Dear Counsel:

I am writing to follow up on our telephone conference of September 7, 2004, regarding the scope of the Covenant Not to Sue that Columbia filed on September 1, 2004 ("Covenant"). At the suggestion of the Court, I am memorializing the clarifications that we provided during our telephone conference.

1. The Covenant applies to any claim of any reissued or reexamined version of the '275 patent that is the same as, or substantially identical to, a claim of the '275 patent as it currently reads. The term "substantially identical" is intended to have the same meaning as that term is used in 35 U.S.C. § 252. The Covenant does not apply to any other claim of any reissued or reexamined version of the '275 patent.
2. The Covenant applies to any product currently made, used, offered for sale, sold, or imported by plaintiffs, or any product that was made, used, offered for sale, sold, or imported by plaintiffs prior to the date of the Covenant. Thus, by way of example, Rituxan is a product currently made and sold by Genentech. Columbia will not sue Genentech for infringement of the '275 patent as it currently reads, or seek royalties under the license agreement on the basis of the '275 patent as it currently reads, with respect to Rituxan at any time now or in the future.
3. The Covenant applies only to plaintiffs in the pending actions. The Covenant does not apply to their affiliates or customers.
4. The Covenant does not apply to any claim in any patent that may issue in the future based upon the pending '159 application, irrespective of whether plaintiffs contend that such claim is the same as, or substantially identical to, a claim of the '275 patent as it currently reads.

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Counsel of Record for Plaintiffs\*  
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During our telephone conference on September 7, plaintiffs also inquired whether Columbia was maintaining the position that their license agreements have been terminated. We will address that issue in a separate letter.

If you have any additional questions concerning the scope of the Covenant, please do not hesitate to contact me.

Very truly yours,



David I. Gindler

cc: Wayne Barsky, Esq.

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**September 10, 2004**

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September 15, 2004

**VIA E-MAIL**

To: Counsel of Record for Plaintiffs\*

Re: In re Columbia University Patent Litigation, MDL No. 1592

Dear Counsel:

I am writing to follow up regarding the Covenant Not to Sue that Columbia filed on September 1, 2004 ("Covenant"). I sent a letter on September 10, 2004, responding to various inquiries concerning the scope of the Covenant. Please let me know if you have any additional questions so that we can eliminate any factual issues that you believe may exist concerning the scope of the Covenant.

Very truly yours,



David I. Gindler

cc: Wayne Barsky, Esq.

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Sep-15-2004 03:19pm From:PILLSBURY-WINTHROP LLP

4159837396

T-313 P.002/005 F-929



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September 15, 2004

Kirke M. Hasson  
Phone: 415.983.1077  
kirke.hasson@pillsburywinthrop.com

VIA FACSIMILE

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Re: *Amgen, Inc. v. Columbia University litigation, MDL-1592*

Dear Counsel:

Thank you for David Gindler's letter today inviting additional clarification of the Covenant. Plaintiffs request further clarification of the Covenant in seven categories:

1. "any product currently made, used, offered for sale, sold, or imported, or any product that was made, used, offered for sale, sold, or imported" (Covenant), and "by way of example, Rituxan is a product currently made and sold by Genentech" (Letter, Sept. 10, 2004). Please confirm:

(a) The Covenant extends not only to vials or lots that were manufactured by September 1, 2004, but also to vials or lots of the same product manufactured at any time in the future, and to the use and sale of such material.

(b) The Covenant extends to all proteins now sold (rituximab, epoetin alfa, etanercept, etc.), not merely the brand name products marketed.

(c) The Covenant extends to all proteins now sold, even if changes are later made in the process by which such a protein is manufactured.

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Sep-15-2004 03:19pm From-PILLSBURY-WINTHROP LLP

4159837396

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David I. Gindler, Esq.  
Wayne M. Barsky, Esq.  
September 15, 2004  
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(d) The Covenant extends to all proteins now sold, even if a new construct or new transformed cells are later created to express any such protein.

2. The Covenant refers to "any product." The '275 patent refers to transformed cells (e.g., '275 patent, claim 1), constructs (e.g., '275 patent, claim 20) and methods (e.g., '275 patent, claim 14). Please confirm:

(a) The Covenant extends to all transformed cells made by September 1, 2004, whether or not amplification of DNA I or DNA II has occurred.

(b) The Covenant extends to all constructs made by September 1, 2004.

(c) The Covenant extends to all proteins expressed before September 1, 2004 using such transformed cell or construct or method.

(d) The Covenant extends to the continued production, use or sale after September 1, 2004, of such cells, constructs and proteins.

3. "The issue of new products" (RT 9/9/04, 29:24). Please confirm:

(a) The Covenant extends to the future manufacture, use, sale, etc. of anything a plaintiff had produced by September 1, 2004, such as a transformed cell, a construct, or a cell line that had been made by September 1, 2004, regardless of whether that thing had yet led to any commercially sold product.

(b) As an example, the Covenant extends to the future manufacture, use, sale, etc. of a protein that a plaintiff had made by September 1, 2004, or of a construct, transformed cell, or cell line expressing that protein, where the protein was in pre-clinical or clinical trials on that date.

4. "prior to the date of this covenant" (Covenant).

Please confirm that, if a scientist at one of the plaintiffs creates for the first time after September 1, 2004, a construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant extends to:

(a) such construct or cotransformed cell.

(b) methods using such construct or cotransformed cell.

(c) a protein produced using such construct or cotransformed cell.

Sep-15-2004 03:19pm From:PILLSBURY-WINTHROP LLP

4159837396

T-313 P.004/005 F-828



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David I. Gindler, Esq.  
Wayne M. Barsky, Esq.  
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Page 3

5. "This covenant is limited to the '275 patent as it presently reads and does not apply to any other patent, whether related or unrelated to the '275 patent. Specifically, this covenant does not apply to any reissued or reexamined version of the '275 patent that may issue in the future or to any patent that may issue from United States Patent Application No. 08/477,159" (Covenant). "The Covenant applies to any claim of any reissued or reexamined version of the '275 patent that is the same as, or substantially identical to, a claim of the '275 patent as it currently reads" (Letter, Sept. 10, 2004). "The Covenant does not apply to any claim in any patent that may issue in the future based upon the pending '159 application, irrespective of whether plaintiffs contend that such claim is the same as, or substantially identical to, a claim of the '275 patent as it currently reads" (*Id.*). Please confirm:

(a) The September 10, 2004 letter was a modification (not merely a "clarification") of the Covenant, in stating that "The Covenant applies to any claim of any reissued or reexamined version of the '275 patent that is the same as, or substantially identical to, a claim of the '275 patent as it currently reads."

(b) The Covenant extends to any claim in any patent that may issue in the future based upon the pending '159 application, if that claim is actually (not merely "contended" to be) identical or substantially identical to a claim of the '275 patent as it currently reads.

(c) Other than the '159 application and the '275 reissue, no pending patent applications exist that claim priority to U.S. Application Serial No. 06/124,513.

6. "The Covenant does not apply to [plaintiffs'] affiliates or customers" (Letter, Sept. 10, 2004). Please confirm that a plaintiff's rights under the Covenant are transferable by the plaintiff with the product. In other words, please confirm that the Covenant applies to a covered product if, for example, a plaintiff elects to have the product manufactured for it by an affiliate or third party, or sold by an affiliate or third party. Similarly, please confirm that the Covenant applies to a covered product if a plaintiff sells its business in the product to a third party.

7. Columbia "covenants . . . not to assert any claim of patent infringement" (Covenant). Please confirm that this extends to activity by a plaintiff that could be considered to be contributory infringement or inducement of infringement of the '275 patent.



Sep-15-2004 03:19pm From-PILLSBURY-WINTHROP LLP

4159837396

T-313 P.005/005 F-929




PILLSBURY WINTHROP LLP

David I. Gindler, Esq.  
Wayne M. Barsky, Esq.  
September 15, 2004  
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Plaintiffs would appreciate Columbia's written confirmation on these points as soon as possible tomorrow, and no later than 5:00 pm PST. If you would like to discuss these issues, please let us know when.

Very truly yours,



Kirke M. Hasson

cc: All plaintiffs' counsel

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September 17, 2004

VIA E-MAIL

To: Counsel of Record for Plaintiffs\*

Re: In re Columbia University Patent Litigation, MDL No. 1592

Dear Counsel:

I am writing in response to the letter from Kirke M. Hasson dated September 15, 2004, which requests on behalf of plaintiffs that Columbia provide certain clarifications of the Covenant Not to Sue filed on September 1, 2004 ("Covenant"). I will respond to the requests in the same order and with the same numerical references as in Mr. Hasson's letter.

1(a). "Covered products" as defined in the Covenant extends not only to vials or lots of such product that were manufactured by a plaintiff on or before September 1, 2004, but also to vials or lots of the same product manufactured by such plaintiff at any time in the future, and to the use and sale of such product.

1(b). "Covered products" as defined in the Covenant extends to all proteins on sale by a plaintiff on or before September 1, 2004, not merely the brand name products that are marketed.

1(c). "Covered products" as defined in the Covenant extends to all proteins on sale by a plaintiff on or before September 1, 2004, even if changes are later made in the process by which such protein is manufactured.

1(d). "Covered products" as defined in the Covenant extends to all proteins on sale by a plaintiff on or before September 1, 2004, even if such plaintiff uses a new DNA construct or a new transformed cell created after September 1, 2004, to express any such protein.

2(a). "Covered products" as defined in the Covenant extends to all transformed cells made on or before September 1, 2004, whether or not amplification of DNA I or DNA II has occurred.

2(b). "Covered products" as defined in the Covenant extends to all DNA constructs made on or before September 1, 2004.

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Counsel of Record for Plaintiffs\*

September 17, 2004

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2(c). "Covered products" as defined in the Covenant extends to all proteins expressed on or before September 1, 2004, made using the transformed cells or DNA constructs referenced in 2(a) and 2(b) or a method covered by the '275 patent as it currently reads.

2(d). The Covenant extends to the continued production, use or sale after September 1, 2004, of the transformed cells, DNA constructs, and proteins referenced in 2(a), 2(b), and 2(c).

3(a). The Covenant extends to the future manufacture, use, or sale by a plaintiff of anything that such plaintiff had produced on or before September 1, 2004, such as a transformed cell, a DNA construct, or a cell line that had been made on or before September 1, 2004, regardless of whether that thing had yet led to any commercially sold product.

3(b). The Covenant extends to the future manufacture, use, or sale by a plaintiff of a protein that such plaintiff had made on or before September 1, 2004, or of a DNA construct, transformed cell, or cell line expressing that protein, where the protein was in pre-clinical or clinical trials on or before that date.

4(a). If a scientist working at a plaintiff creates for the first time after September 1, 2004, a DNA construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant does not extend to such DNA construct or cotransformed cell, unless such protein encoded by the DNA construct or cotransformed cell was on sale by such plaintiff on or before September 1, 2004.

4(b). If a scientist at one of the plaintiffs creates for the first time after September 1, 2004, a DNA construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant does not extend to methods of using such DNA construct or cotransformed cell, unless such protein encoded by the DNA construct or cotransformed cell was on sale by such plaintiff on or before September 1, 2004.

4(c). If a scientist at one of the plaintiffs creates for the first time after September 1, 2004, a DNA construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant does not extend to a protein produced using such DNA construct or cotransformed cell, unless such protein encoded by the DNA construct or cotransformed cell was on sale by such plaintiff on or before September 1, 2004.

5(a). The letter dated September 10, 2004 ("September 10 Letter") was not a modification of the Covenant in stating that: "The Covenant applies to any claim of any

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Counsel of Record for Plaintiffs\*  
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reissued or reexamined version of the '275 patent that is the same as, or substantially identical to, a claim of the '275 patent as it currently reads." The quoted statement is simply the legal consequence of the Covenant, as explained in *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631 (Fed Cir. 1991), and *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852 (Fed. Cir. 1999).

5(b). The Covenant does not extend to any claim in any patent that may issue in the future based on the '159 application, without exception.

5(c). Other than the '159 application and the '275 patent reissue application, there are no pending patent applications that claim priority to U.S. Application Serial No. 06/124,513.

6. Columbia cannot confirm any of these statements with respect to possible relationships that plaintiffs may elect to have in the future with unidentified third parties regarding "covered products." The statements are simply too theoretical. Your letter does not identify any such current relationship between a plaintiff and a third party regarding a "covered product." If any plaintiff has a current contractual (or other) relationship with a third party regarding a "covered product" that such plaintiff believes creates an actual case or controversy with Columbia concerning the validity, enforceability, or infringement of the '275 patent as it currently reads, please identify such third party and the nature of the relationship and Columbia will consider whether it is necessary to take some action to eliminate an actual case or controversy.

7. The phrase "any claim of patent infringement" as used in the Covenant includes direct infringement, contributory infringement, and inducing infringement.

If you believe that there are any other issues concerning the Covenant that require clarification, please contact me so that we may attempt to resolve them promptly. I would appreciate your informing me whether plaintiffs are now prepared to stipulate to the relief sought in Columbia's Motion to Dismiss. I request that counsel for any plaintiff who is not prepared to stipulate to the relief sought in Columbia's Motion to Dismiss advise us promptly as to the basis for that opinion so that we may make every effort to eliminate or narrow the issues in dispute.

Very truly yours,



David I. Gindler

cc: Wayne Barsky, Esq.

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September 17, 2004

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